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10/600,584	06/19/2003	Robert W. Blakesley	55670DIV(45858)	5497
21874 7590 69/26/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874			EXAMINER	
			BABIC, CHRISTOPHER M	
BOSTON, MA 02205		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/600,584 BLAKESLEY ET AL Office Action Summary Examiner Art Unit CHRISTOPHER M. BABIC 1637 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 09 May 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 26.27.33-37 and 39-48 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 26, 27, 33-37, and 39-48 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

information Disclosure Statement(s) (PTO/S5/06)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

### DETAILED ACTION

### Status of the Claims

Claim(s) 26, 27, 33-37, and 39-48 are pending. The following Office Action is in response to Applicant's communication dated May 9, 2008.

## Claim Rejections - 35 USC § 112 - Indefiniteness - New Grounds

The following new grounds of rejection is made in view of Applicant's amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 26, 27, 33-37, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claims are indefinite because it is unclear whether the "matrix or solid medium" recited in step B is the same "dry matrix or solid medium" recited in step A. Furthermore, it is unclear which "solid matrix/medium", recited in either step A or B, claims 33, 37, and 39 are referencing.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 26, 27, 33, 34, 37, 39, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujishiro (JP 07-250681; 10 March 1995; translation provided by JPO @ http://www.ipdl.inpit.go.jp/).

With regard to claim(s) 26, 27, 37, 39, 41, and 42, Fujishiro teaches methods for the isolation of plasmid DNA from bacterial cells (abstract; pg. 1 of translation, for example). Specifically, Fujishiro teaches a method comprising: a) providing a dry matrix (see discussion of [0007]-[0011] below) (the amended claims require a dry matrix OR a dry solid medium; thus the said dry solid medium comprising components i)-iii) is required by only one of two possible method choices); b) contacting a matrix with a sample comprising a host cell or virus containing said vector or vectors ([0007]-[0011] of translation, Fujishiro teaches the growing of plasmid containing E. coli., application of the E. coli to a solid medium comprising a "trap filter," and the lysis of the E. coli, for example); and b) isolating all or a portion of said vector or vectors from said medium ([0012]-[0013] of translation, Fujishiro teaches the elution of plasmid DNA from the solid medium, for example).

With regard to claim(s) 33 and 34, Fujishiro teaches polymeric and cellulosebased matrices [0016]-[0017], polethylene, cellulose acetate, for example). Application/Control Number: 10/600,584 Page 4

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# Response to Arguments

Applicant's arguments have been addressed in the above rejection. The rejection is maintained.

## Claim Rejections - 35 USC § 103 - Maintained

As initial matter, it is noted that the statement of rejection presented below includes claims 40-42, correcting an inadvertent error the statement of rejection presented in the Office Action dated January 24, 2008. Claims 40-42 were examined previously along with claims 47 and 48, as they recite similar limitations, and correctly marked as rejected in the conclusion statement and PTO-326 form in the Office Action dated January 24, 2008.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be needlived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26, 27, 33-37, and 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. ("Bacterial typing: storing and processing of stabilized reference bacteria for polymerase chain reaction without preparing DNA--an example of an automatable procedure" Anal Biochem. 1997 May 1;247(2):223-7) in view of Burgoyne (U.S. 5,496,562), and in view of Kahn et al. (Plasmid cloning vehicles derived from plasmids CoIE1, F, R6K, and RK2" Methods Enzymol. 1979;68:268-80).

The claims are drawn to a method of isolation of vectors from host cells by contacting the host cells with a solid medium. In some embodiments the solid medium protects the vector from degradation, is made of cellulose or a micromesh plastic, the host cells are in solution, and the solid medium comprises urate salt, a chelating agent, and an anionic detergent.

Rogers et al. shows in the abstract and throughout recovery of DNA from bacterial liquid cultures by application of the bacterial culture to FTA® blood storage medium. Figures 1 and 2 show positive results of PCR assay of bacterial DNA from FTA® media to which bacterial cultures were applied. Rogers et al. shows that the DNA is stable for at least 1.6 years after application to the FTA® media on page 226. Rogers et al. does not show use of bacteria comprising vectors, media comprising micromesh

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plastic, and Rogers et al. does not detail the composition of the chemicals in the FTA media. Rogers et al. states on page 223 that FTA® medium is described in Burgoyne (U.S. Patent No. 5,496,562).

Burgoyne shows the components of a solid medium for preserving DNA from blood cells in columns 2-4, including use of a solid support such as cellulose or a micromesh of a synthetic plastic (column 2, lines 21-23), urate, an anionic detergent, and a chelating agent (column 2, lines 54-64 and column 3, lines 18-26). Burgoyne shows the application and storage of isolated plasmids on the solid medium in Example 2, columns 4-6. Burgoyne discloses application of plasmid pUC19 and recovery of approximately 100% of the applied plasmid from the solid matrix in column 6. Burgoyne claims a method of application of generic DNA and recovery of the applied DNA from a solid matrix in at least claim 6.

Kahn et al. reviews plasmid cloning vectors, and shows that such vectors are replicated in bacteria in the abstract and throughout. Kahn et al. shows on page 268 that plasmid vectors are useful for cloning and maintenance of foreign DNA.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rogers et al. by use of bacteria comprising vectors because Burgoyne shows that the solid media used by Rogers et al. can be used for long term storage and recovery of plasmids, and Kahn et al. shows that bacterial plasmid vectors are useful for cloning and maintenance of foreign DNA.

### Response to Arguments

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Applicant's arguments have been fully considered but they are not persuasive. Applicant asserted identical arguments presented in the response dated October 12, 2007. Thus, the rejection is maintained for the same reasons presented in the Office Action dated January 24, 2008.

#### Conclusion

#### No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/ Primary Examiner, Art Unit 1637

/Christopher M. Babic/ Patent Examiner Art Unit 1637 Technology Center 1600